NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

April 20, 2004

Division of Dockets Management (HRA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

RE: [Docket No. 1992N-0297] Delay of Effective Date of Certain PDMA Regulations

The National Association of Chain Drug Stores (NACDS) is writing in support of the delay of the effective date of certain sections of the Prescription Drug Marketing Act (PDMA), namely Sections 203(u) and 203.50 (21 CFR 203.3(u) and 203.50) until December 2006 (see 69 Fed. Reg. 8105, February 23, 2004). These sections relate to pedigree requirements for wholesale distributors of prescription drugs that are not authorized distributors of record.

413 North Lee Street
P.O. Box 1417-D49
Alexandria, Virginia
22313-1480

NACDS membership includes more than 210 chain companies that operate 35,000 community retail pharmacies. Chain pharmacies are the largest purchasers and providers of outpatient prescription drugs in the United States.

The ability to ensure the authenticity of prescription drugs is essential in preventing the distribution or dispensing of counterfeit prescription drugs. NACDS strongly believes that a properly structured electronic pedigree system for tracking and tracing prescription drug products would help enhance the integrity of the prescription drug distribution system. Such a process will likely be in place at the case and pallet level throughout the distribution system by 2007.

Ultimately, ensuring drug authenticity will require the development of a digital track and trace capabilities across the U.S. prescription drug supply chain. Future track and trace technologies that ensure drug authenticity will require the development of industry minimum standards and adoption of new IT systems infrastructure based on cost/benefit analyses. A well-choreographed approach to industry regulation, changes in business practices, and adoption of new technology is necessary for enabling track and trace capabilities in both the short-and longer-terms. These processes are being developed at this time.

Unfortunately, implementation of the current PDMA pedigree requirements would do little to reduce the risk of counterfeiting, but would add significant administrative burdens to manufacturers, wholesalers, and pharmacies. For example, the current PDMA has loopholes that allow diverted or counterfeit drugs to enter the system, severely crippling the ability to provide trusted authentication throughout the supply chain. ADRs (Manufacturers' Authorized Distributors of Record) are not required to obtain authentication documentation from manufacturers, making comprehensive

(703) 549-3001
Fax (703) 836-4869
www.nacds.org

documentation impossible in this channel. ADR is loosely defined, enabling the majority of wholesalers to attain an ADR status

Paper pedigree documents are expensive and ineffective because they are costly to maintain and easier to counterfeit than the drugs themselves. Current business practices do not support an industry-wide ability to track and trace drug flow because transaction records are not required, preventing a complete picture of product flow across the supply chain. Requiring the industry to divert critical resources now for a relatively ineffective paper based pedigree system will delay the development of a much more effective electronic-based system

We believe that other steps can be implemented during the two and a half year period between now and December 2006 that will help to reduce the risk of counterfeit drugs entering the United States distribution system without using an expensive system of paper pedigrees. We appreciate the agency's recognition of this fact and strongly support the extension of the implementation date of these sections of PDMA.

We appreciate the opportunity to submit comments on this important issue.

Sincerely,

S. Lawrence Kocot
Senior Vice President and General Counsel